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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,694	07/09/2003	Sharlene Adams	10248.70023US00	1643
7590	10/14/2005			
Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			EXAMINER LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,694

Applicant(s)

ADAMS ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Continuation of Disposition of Claims:

Claims pending in the application are

1-13,40,44,61,77,94,112,129,164,172,192,198,267,276,281,283,287,290,294,299,309,362-364,405,437 and 467.

Continuation of Disposition of Claims:

Claims subject to restriction and/or election requirement are

1-13,40,44,61,77,94,112,129,164,172,192,198,267,276,281,283,287,290,294,299,309,362-364,405,437 and 467.

- Pursuant to preliminary amendment, the following claims have been cancelled:
14-39, 41-43, 45-60, 62-76, 78-93, 95-111, 113-128, 130-163, 165-171, 173-191, 193-197, 199-266, 268-275, 277-280, 282, 284-286, 288-289, 291-293, 295-298, 300-308, 310-361, 365-404, 406-436, 438-466, 468-484.
- Pursuant to preliminary amendment, the following claims have been amended: 1, 13, 40, 44, 61, 77, 94, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309, 362-364, 405, 437, 467
- The following claims are now pending: 1-13, 40, 44, 61, 77, 94, 112, 129, 164, 172, 192, 198, 267, 276, 281, 283, 287, 290, 294, 299, 309, 362-364, 405, 437, 467



Restriction to one of the following inventions is required under 35 U.S.C. §121:

- 1) Claims 1-12, 362-364, drawn to a method of treating a condition characterized by abnormal cell proliferation
- 2) Claims 13 and 164, drawn to a method of treating an infectious disease.
- 3) Claims 40 and 44, drawn to a preparation.
- 4) Claims 61, 77, 94, drawn to a kit.
- 5) Claims 112, 129, 172, 192, 198, 294, 299, 309, drawn to a method of modulating an immune response.
- 6) Claim 267, drawn to a method of treating an IFN-responsive condition.
- 7) Claim 276, drawn to a method of treating cancer by administering a compound of formula I in combination with an enzyme inhibitor.
- 8) Claim 281, drawn to a method of treating a cardiovascular disease.

- 9) Claim 283, drawn to a method of preventing drug resistance.
- 10) Claims 287 and 290, drawn to a method of shortening a vaccine course.
- 11) Claim 405, drawn to a composition comprising a compound of formula I and an antibody.
- 12) Claim 437, drawn to a composition comprising a compound of formula I and a cancer antigen.
- 13) Claim 467, drawn to a composition comprising a compound of formula I and a microbial antigen.

. . . .

The claimed inventions are distinct.

Inventions 3 and {1, 2, 5, 6, 8, 9, 10} are actually not related as product and process of use.

The reason is that Group 3 requires limitations that are not present in the method claims.

However, if it had been the case that the method claims contained the same limitations as the composition claims, then the following form paragraph would have applied:

The inventions in question are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)).

Nevertheless, in the event that Group 3 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination provided that

the limitations present in the claims (drawn to the composition) are incorporated into the method claims [*In re Ochiai* (37 USPQ2d 1127)].

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Regardless of which group is chosen for initial examination, election of a specific compound is required, with all substituent and integer variables fully accounted for. The stereochemistry of each amino acid should also be indicated.

In the event that Group 1 is chosen for initial examination, election of the following is required (in addition to the specific compound referred to immediately above):

- (a) a specific disease such as non-Hodgkin's lymphoma or basal cell carcinoma or a neurofibrosarcoma;
- (b) one of the following: (i) administration by injection or (ii) administration of an enterically coated form, and
- (c) a specific composition that is to be administered, with all ingredients accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.



Serial No. 10/616,694
Art Unit 1654

-6-

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800